

LARGE SCALE PREPARATION OF ALPHA-1 PROTEINASE INHIBITOR AND USE THEREOF

ABSTRACT OF THE DISCLOSURE

A process suitable for processing scaled-up amounts of source material in the range of tens of kilograms for the purification of alpha-1 proteinase inhibitor (API) from a mixture of unpurified proteins is provided. More particularly, a process for the purification of API from blood plasma or from plasma fractions to obtain pharmaceutical grade API on a commercial scale is provided. The API produced by the process is highly pure (at least 90% API out of the total protein) and highly active (at least 90% active API). Pharmaceutical compositions comprising the purified API and methods of using same are also described.